PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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Rec.: - 7 FEB. 2005

Opbergen:

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Applicant's or agent's file reference P26395PC00/JPO RRT	Date of mailing *(day/month/year)* 08.02.2005
	IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/NL 03/00699	16.10.2003	18.10.2002

Applicant
ADVANCED PROTECTIVE INJECTION SYSTEMS B.V. et Al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Koestel, G Tel. +31 70 340-3544

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P26395PC00/JPO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/NL 03/00699	16.10.2003	18.10.2002
International Patent Classification (IPC) or both national classification and IPC		
A61M5/32		
Applicant		
ADVANCED PROTECTIVE INJECTION SYSTEMS B.V. et Al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
10.05.2004	08.02.2005
Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Sedy, R Telephone No. +31 70 340-2978

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/NL 03/00699

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-18 as originally filed

Claims, Numbers

1-19 received on 03.01.2005 with letter of 03.01.2005

Drawings, Sheets

1/11-11/11 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 17-19

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 17-19

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-15
	No:	Claims	16
Inventive step (IS)	Yes:	Claims	1-15
	No:	Claims	16
Industrial applicability (IA)	Yes:	Claims	1-16
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:
D1: US-A-5 221 262 (KITE JOHN P) 22 June 1993 (1993-06-22)

1. **Claims 1-15**

1.1 The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (see column 3, line 62 - column 4, line 43, Figures 1,2 and 4)(the references in parenthesis applying to this document):

an injection syringe (10) with retractable needle (18) having
- a liquid container (11) with an outlet opening,
- a needle (18) with needle mount (22) which is secured on the outlet opening of the liquid container (11);
- a piston (32) movable inside the liquid container (11) and having a piston head (39), to which a piston rod (34) is secured, wherein the needle mount (22) of the needle (18) and the piston head (39) comprise coupling means which are designed so that they are unmistakably couplable to one another by moving the piston (32) towards the outlet opening;

a blocking is provided which is designed to block the needle mount (22) in the outlet opening, the blocking means being designed in the form of one or more resilient lugs (31) on the needle mount (13) which are received in corresponding recesses in the liquid container (11) (needle support (17) is fixed to needle mounting (13) of container (11) - see column 4, lines 2-4).

1.2 The subject-matter of claim 1 therefore differs from this known injection syringe in that:

the blocking means can only be unblocked by retraction of the needle mount and needle into the liquid container by movement of the piston away from the outlet opening after the needle mount has been coupled to the piston head,

the coupling means of the needle mount of the needle comprises at least two ribs which are connected to one another at a connection point on the side which faces the piston head,

which ribs of the needle mount are movable closer together, when the needle is retracted into the liquid container by movement of the piston away from the outlet

opening after the piston head has been coupled to the needle mount.

Consequently, the subject-matter of claim 1 is new with respect to Article 33(2) PCT.

The technical problem to be solved by the present application may therefore be regarded as providing an injection syringe which needle does not contain the risk of injury for the patient.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reason:

the lugs which are provided on the ribs maintain the needle mount secured on the outlet opening of the liquid container during the inward stroke of the piston and also during the coupling of the piston with these ribs at the end of the inward piston stroke. It is only at the moment at which the piston is retracted that a disengagement between the ribs and the needle mount takes place.

A premature disconnection of the needle mount from the outlet opening is thus prevented.

Dependent **claims 2-15** specify advantageous embodiments of the subject-matter of claim 1.

2. **Claim 16**

The subject-matter of claim 16 is not new in view of D1, compare paragraph 1.1 above. The requirements of Article 33(2) PCT are thus not met. Moreover, claim 16 is formulated such that the needle mount is intended to be *suitable for* an injection syringe according to any preceding claim without indicating any specific features which would make the needle mount suitable for such a purpose. Additionally, the syringe of claim 1 already comprises a needle mount. As such, claim 16 does not meet the requirements of Article 6 PCT.

3. Remarks

3.1 Claim 16 defines a needle mount intended to be *suitable for* an injection syringe (see point 2 above). As such, there are no technical features which would clearly define the scope of this claim.

10/531644 NL0300699
JC13 Rec'd PCT/PTO 15 APR 2005

With letter to the EPO dated January 3, 2005

EPO - DG 1
03. 01. 2005
(108)

AMENDED CLAIMS

1. Injection syringe (1) with retractable needle (2), at least comprising:

- a liquid container (3) with an outlet opening (4);
- a needle (2) with needle mount (8) which is secured on the outlet opening (4) of the liquid container (3);
- a piston (5) movable inside the said liquid container (3) and having a piston head (6), to which a piston rod (7) is secured, wherein the needle mount (8) of the needle (2) and the piston head (6) comprise coupling means which are designed so that they are unmistakably couplable to one another by moving the piston (5) towards the outlet opening (4);

characterized in that

a blocking means (14) is provided which is designed to block the needle mount (8) in the outlet opening (4), the blocking means (14) being designed in the form of one or more resilient lugs on the needle mount (8) which are received in corresponding recesses (18) in the liquid container (3),

which blocking means (14) can only be unblocked by retraction of the needle mount (8) and needle (2) into the liquid container (3) by movement of the piston (5) away from the outlet opening (4) after the needle mount (8) has been coupled to the piston head (6),

and wherein the coupling means of the needle mount (8) of the needle (2) comprise at least two ribs (15) which are connected to one another at a connection point (16) on the side which faces the piston head (6), the one or more lugs being provided on the ribs (15),

which ribs (15) of the needle mount (8) are movable closer together, when the needle (2) is retracted into the liquid container (3) by movement of the piston (5) away from the outlet opening (4) after the piston head (6) has been coupled to the needle mount (8).

2. Injection syringe (1) according to claim 1, in which the ribs (15) are resilient.

3. Injection syringe (1) according to one of the proceeding claims, in which the ribs (15) partially surround a continuous opening (21).

4. Injection syringe (1) according to one of the proceeding claims, in which the connection point (16) comprises a hinged connection, in particular an integral hinge.

5. Injection syringe (1) according to one or more of the preceding claims, in which at least one of the ribs (15) of the needle mount (8) has a curvature in the direction of the longitudinal axis of the liquid container (3).

6. Injection syringe (1) according to one or more of the preceding claims , in which at least one of the ribs (15) of the needle mount (8) comprises a coupling element (17) which is directed towards the wall of the liquid container (3).

7. Injection syringe (1) according to claim 6, in which at least two of the ribs (15) of the needle mount (8) comprise a coupling element (17) which is directed towards the wall of the liquid container (8), at least one of the coupling elements (17) being at a different distance from the connection point (16) compared to the at least one other coupling element (17).

8. Injection syringe (1) according to one or more of the preceding claims, in which the coupling means of the needle mount (8) comprise three ribs (15) which are connected to one another at the connection point (16) on the side which faces the piston head (6).

9. Injection syringe (1) according to one or more of the preceding claims, in which the needle mount (8) is provided, on its side which faces the piston head (6), with a coupling member (20) for coupling to the piston head (6), which coupling member (20) is preferably connected to the connection point (16).

10. Injection syringe (1) according to one or more of the preceding claims, in which the injection syringe (1) also comprises a spring member (23)for forcing the needle mount (8) with needle (2) into the liquid container (3) after the blocking means (14) has been unblocked.

11. Injection syringe (1) according to claim 10, in which the spring member (23) forms part of the needle mount (8).

12. Injection syringe (1) according to claim 10 or 11, in which the spring member (23) is blocked by a spring member-blocking means (24).

13. Injection syringe (1) according to claim 12, in which the spring member-blocking means (24) interacts with a protective cap (25) for the purpose of blocking the spring member (23).

14. Injection syringe (1) according to claim 12 or 13, in which the spring member-blocking means (24) forms part of a securing element (22).

15. Injection syringe (1) according to one or more of the preceding claims 10-14, in which the spring member (23) is in a prestressed state.

16. Needle mount (8) for an injection syringe (1) according to one or more of the preceding claims 1-15.

17. Securing element (22) for an injection syringe according to one of the preceding claims 12-14, which securing element (22) secures the needle mount (8) to the liquid container (3) from the outside, the securing element (22) being provided with the spring member-blocking means (24).

18. Securing element (22) according to claim 17, in which the securing element (22) is provided with the spring member (23) which is in a prestressed state.

19. Set comprising a protective cap (25), needle mount (8) according to claim 16 with needle (2), spring member (23) and a securing element according to claim 17 or 18.